

REMARKS

The Office requires restriction, citing 35 U.S.C. § 121, to one of the following inventions:

- I. Claims 1-14, which are drawn to a composition (pharmaceutical) for enhancing contrast of one or more areas of a subject via CT comprising PEGylated liposomes containing iodinated compounds, classified in class 424, subclass 9.45.
- II. Claims 15-21, which are drawn to a method comprising forming sterically stabilized liposomes containing iodinated compounds, classified in class 424, subclass 9.4.
- III. Claims 22-24, which are drawn to a method of imaging a subject with sterically stabilized liposomes containing nonradioactive contrast enhancing agents, classified in class 424, subclass 9.4.
- IV. Claims 24-33, which are drawn to a composition comprising a first and polymer-derivatized second lipid, excipients and a nonradioactive contrast enhancing agent, classified in class 424, subclass 9.4.

In response to the Restriction Requirement, Applicants elect, with traverse in part, the invention designated by the Office as Group IV (claims 25-33). More specifically, Applicants elect Group IV (claims 25-33) with traverse as it relates to Group I (claims 1-14). Applicants elect Group IV without traverse as it relates to Group II (claims 15-21) and Group III (claims 22-24).

THE OFFICE ACTION DOES NOT ESTABLISH A PRIMA FACIE CASE REQUIRING RESTRICTION UNDER 35 U.S.C. § 121 AS IT RELATES TO GROUPS I AND IV

The statutory basis for restriction and double patenting is found in 35 U.S.C. § 121, which states in relevant part, “if two or more *independent and distinct* inventions are claimed in one application, the Commissioner *may* require the application to be restricted to one of the inventions.” (emphasis added). Thus, the statutory basis for a proper restriction requires a showing that the inventions are both independent and distinct.

THE CLAIMS OF GROUPS I AND IV ARE DEPENDENT

Applicants respectfully submit that Group I (claims 1-14) and Group IV (claims 25-33) are dependent upon each other. The M.P.E.P defines “independent” to mean that no disclosed relationship exists between the multiple subjects claimed. In other words, the claimed inventions lack any commonality in “design, operation, or effect.” M.P.E.P. § 802.01.

In the case at hand, Group I and Group IV are each directed toward a composition comprising, among other things, a sterically stabilized liposome and a nonradioactive contrast enhancing agent. Exemplary compositions may contain, inter alia, lipids or phospholipids and polymer-derivatized lipids or phospholipids (such as PEGylated lipids or phospholipids). None of claims 1-9 or 11 of Group I specifically require PEGylated liposomes; and none of claims 25-33 of Group IV even arguably exclude PEGylated liposomes. Exemplary compositions may also contain nonradioactive contrast enhancing agents (see claim I of Group I and claim 25 of Group IV), which necessarily may include iodinated compounds. Accordingly, the claimed subjects are connected by a common element in “design, operation and effect.” As such, the claims are dependent.

CONCLUSION

With the above election, the Application is now in condition for examination and allowance on the merits. Applicants appreciate the Examiner’s attention to this matter. While no additional fees are believed necessary, please charge any additional fees or credit any overpayments to Deposit Account No. 02-2051, referencing Attorney Docket No. 27428-4.

In re application of : Annapragada et al.

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Respectfully submitted,

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